DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 14, 2015

Weihai Hongyu Nonwoven Fabric Products Co., Ltd.
C/O Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
Post Office Box 120-119
Shanghai, 200120
CHINA

Re: K141324
Trade/Device Name: Hongyu Disposable Surgical Drapes
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape
Regulatory Class: II
Product Code: KKX
Dated: March 18, 2015
Received: March 19, 2015

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141324

Device Name
HONGYU Disposable Surgical Drapes

Indications for Use *(Describe)*

HONGYU Disposable Surgical Drapes are devices made of synthetic material intended to be used as a protective patient covering to isolate a site of surgical incision from microbial and other contamination. The drape is sterilized using ethylene oxide and is intended for single external use only.

This drape is classified as Level 4 per AAMI Standard PB70 liquid barrier performance and classification of protective apparel and drapes intended for use in health-care facilities.

Models:C-section Drape, Arthroscopy Drape, Bladder Drape, Split (U) Drape, Arm (Wrist) Drape, Miscellaneous Drape, Abdominal Drape, Shoulder Drape, Lithotomy Drape, Neck Drape, Fenestrated Drape, Simple Drape, Extremity Drape, Universal Drape, Head Drape, Craniotomy Drape, Buttock Drape, Dental Drape, ENT Drape, Pediatric Laparotomy Drape, Ophthalmic Drape, Angiography Drape and Articulation Drape.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Section 3 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K141324

1. Date of Submission: April 9, 2015

2. Sponsor Identification

Weihai Hongyu Nonwoven Fabric Products Co., Ltd
9-1 Pudong Rd, Economy and technique area, Weihai, Shandong, 264200, China

Establishment Registration Number: 3008489813

Contact Person: Yanfei Liu
Position: Registration Manager
Tel: +86-631-3636943
Fax: +86-631-3636910
Email: liuyanfei340@163.com

3. Submission Correspondent

Ms. Diana Hong & Mr. Lee Fu
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

4. Proposed Device Identification

Proposed Device Trade Name: HONGYU Disposable Surgical Drapes
Proposed Device Common Name: Surgical Drape

Regulatory Information:
Classification Name: Drape, Surgical
Classification: II;
Product Code: KKX
Regulation Number: 21 CFR 878.4370
Review Panel: General & Plastic Surgery

Intended Use Statement:

HONGYU Disposable Surgical Drapes are devices made of synthetic material intended to be used as a protective patient covering to isolate a site of surgical incision from microbial and other contamination. The drape is sterilized using ethylene oxide and is intended for single external use only.

This drape is classified as Level 4 per AAMI Standard PB70 liquid barrier performance and classification of protective apparel and drapes intended for use in health-care facilities.

Models: C-section Drape, Arthroscopy Drape, Bladder Drape, Split (U) Drape, Arm (Wrist) Drape, Miscellaneous Drape, Abdominal Drape, Shoulder Drape, Lithotomy Drape, Neck Drape, Fenestrated Drape, Simple Drape, Extremity Drape, Universal Drape, Head Drape, Craniotomy Drape, Buttock Drape, Dental Drape, ENT Drape, Pediatric Laparotomy Drape, Ophthalmic Drape, Angiography Drape and Articulation Drape.

5. Predicate Device Identification

510(k) Number: K130404
Product Name: Cardinal Health Tiburon® surgical drape
Manufacturer: Cardinal Health 200, LLC

6. Device Description

HONGYU Disposable Surgical Drapes are devices made of synthetic material intended to be used as a protective patient covering to isolate a site of surgical incision from microbial and other contamination. The drape is sterilized using ethylene oxide and is intended for single external use only.

This drape is classified as Level 4 per AAMI Standard PB70 liquid barrier performance and

classification of protective apparel and drapes intended for use in health-care facilities.

HONGYU Disposable Surgery Drapes offer a variety of surgery drapes (23 types), including C-section Drape, Arthroscopy Drape, Bladder Drape, Split (U) Drape, Arm (Wrist) Drape, Miscellaneous Drape, Abdominal Drape, Shoulder Drape, Lithotomy Drape, Neck Drape, Fenestrated Drape, Simple Drape, Extremity Drape, Universal Drape, Head Drape, Craniotomy Drape, Buttock Drape, Dental Drape, ENT Drape, Pediatric Laparotomy Drape, Ophthalmic Drape, Angiography Drape and Articulation Drape.

The HONGYU Disposable Surgery Drapes have a basic drape. Additionally, each of the drapes has different drape components according to the intended clinical surgery sites, such as the reinforcement, fenestration, single-coating/ double-coating medical tape, PE pouch, PE film and Velcro-style line holders/ tube holders.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

AAMI PB70-2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities
ASTM F1670-08, Standard test method for resistance of material used in protective clothing to penetration by synthetic blood.
16 CFR Part 1610:2008 Standard for the Flammability of Clothing Textiles
ASTM D5034- 09 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
ASTM D 5587- 08 Standard Test Method for Tearing Strength of Fabrics by the Trapezoid Procedure
ISO 9073-10:2003 Textiles Test Methods for Nonwovens- Part 10: Lint and Other Particles Generation in the Dry State
ASTM F 1868- 12 Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate - Part B- Isothermal Evaporative Resistance
ISO 10993-5:2009: Biological Evaluation of Medical Devices- Part 5: Tests for in vitro Cytotoxicity
ISO 10993-10:2010 Biological Evaluation of Medical Devices- Part 10: Tests for irritation and skin sensitization
ISO 11135-1:2007 Sterilization of health care products- Ethylene oxide- Part 1: Requirements for development, validation and routing control of a sterilization process for medical devices
ISO 10993-7: 2008: Biological evaluation of medical device-Part 7: Ethylene oxide sterilization residuals
ASTM F88-05 Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F 1140-00 (2005) Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Package for Medical Applications

ASTM F1929-98(2004) Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

Item		Proposed Device(s)	Predicate Device K130404
Product Code		KXX	KXX
Regulation Number		21 CFR 878.4370	21 CFR 878.4370
Intended Use		HONGYU Disposable Surgical Drapes are devices made of synthetic material intended to be used as a protective patient covering to isolate a site of surgical incision from microbial and other contamination. The drape is sterilized using ethylene oxide and is intended for single external use only. This drape is classified as Level 4 per AAMI Standard PB70 liquid barrier performance and classification of protective apparel and drapes intended for use in health-care facilities.	Cardinal Health Tiburon® surgical drapes are devices made of nature or synthetic material intended to be used as a protective patient covering to isolate a site of surgical incision from microbial and other contamination. The drape is sterilized using ethylene oxide and is intended for single external use only. This drape is classified as Level 4 per AAMI Standard PB70 liquid barrier performance and classification of protective apparel and drapes intended for use in health-care facilities.
Components		Basic drape, Reinforcement, PE pouch, Incise film, Elastomeric film	SAME
Sterile		EO sterilization	EO sterilization
Single Use		Yes	Yes
Resistance to Blood and Liquid Penetration		Level 4 per AAMI PB 70	Level 4 per AAMI PB 70
Fire Protection		Class I	Class I
Biocompatibility	Cytotoxicity	Conform to the requirement of ISO 10993-5 No Cytotoxic Potential under the conditions of study	Conform to the requirement of ISO 10993-5 No Cytotoxic Potential under the conditions of study
	Irritation	Conform to the requirement of ISO 10993-10 No Primary Skin Irritation under the conditions of the study	Conform to the requirement of ISO 10993-10 No Primary Skin Irritation under the conditions of the study
	Sensitization	Conform to the requirement of ISO 10993-10	Conform to the requirement of ISO 10993-10

		Not a Dermal Sensitizer under the conditions of the study	Not a Dermal Sensitizer under the conditions of the study

The HONGYU Disposable Surgical Drapes are determined to be Substantially Equivalent (SE) to the predicate device, Cardinal Health Tiburon® surgical drape.